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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,820	09/20/2005	Norbert Heske	289-PDD-03-09 US	3682
79990 7590 02/03/2009 C. R. Bard, Inc. Bard Peripheral Vascular, Inc. 1415 W. 3rd Street P.O. Box 1740 Tempe, AZ 85280-1740				
EXAMINER STOUT, MICHAEL C				
ART UNIT		PAPER NUMBER		
3736				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,820

Applicant(s)

HESKE ET AL.

Examiner

MICHAEL C. STOUT

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 9/25/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/549,820 filed on 9/20/2005 and is a first action based on the merits of the application. Response to Election/Restriction and Non-Final document(s) filed on 7/31/2008 and 10/17/2007 respectively is/are being considered by the examiner.

Election/Restrictions

Applicant's election with traverse of Group 1 claims 1-4 in the reply filed on 11/29/2008 is acknowledged. The traversal is on the ground(s) that the claims share common aspects and the Applicant disagrees with interpretation of Ouchi (US Pat 6,5414,215). This is not found persuasive because under the common subjected mater of the claimed invention is taught by Ouchi, which under PCT Rule 13.1 and 13.2 is a showing of lack of unity of the invention. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 1-4 are objected to because of the following informalities: Claims 1-4 contain the phrase "characterized in that" which should be replaced with an appropriate phrase such as "wherein" or "comprising" or "further comprising". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meets and bounds of the claims are unclear as the claims lack a preamble and transitional phrases.

Furthermore, the claims comprise several errors including, in particular Claim 1 recites the sealing element releasing the air outlet which lacks antecedent basis. Claim 2, recites "the interior diameter of which is dimensioned" it is unclear wither this is in reference to the coaxial cannula or sealing element. Claim 3 recites the use of the device with a biopsy device, it is unclear whether this is an intended use or an additional structure to the biopsy needle of claim 1 or in reference to the biopsy needle. Claim 3 also recites "the opening" which lacks antecedent basis and it is unclear what structure the opening is referring to. In regards to claim 4, "the cap" lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi (US 6,514,215 B1).

Regarding claim 1, Ouchi teaches a cannula that can be used in tissue, in which for removing tissue are a biopsy needle unit with specimen removal space and a longitudinally movable specimen separating device that coaxially encloses the biopsy needle on the exterior wall (Ouchi teaches a biopsy needle 110 placed inside a specimen separating device 120, Figure 1), and whereby the coaxial cannula has on its proximal end a sealing element that encloses the space between the interior wall of the coaxial cannula and the exterior wall of the specimen separating device, characterized in that the sealing element releases the air outlet when the needle unit is inserted and prevents air from entering after the needle unit has been positioned and a vacuum has been created in the biopsy needle interior space (the coaxial cannula has a sealing element 138 which is capable of releasing air as the needle 110 is inserted and preventing fluid flow when a vacuum is created, see Figures 1-7 and Column 5, line 40 through Column 6, Line 30).

Regarding claim 2, Ouchi teaches a coaxial cannula in accordance with claim 1, characterized in that a hose-type sealing element is pushed over the proximal end of the coaxial cannula tube (the sealing element 138 is pushed over the proximal end of the tube as 110 is inserted), the interior diameter of which is dimensioned so that it leaves open a slight gap between the sealing element and the biopsy needle unit (the sealing element is dimensioned such that upon insertion there is a gap when the needle 110 section 112 or 113 passes through the sealing element), and in that the elasticity of

the sealing element is such that, given slight underpressure in the gap between the exterior wall of the needle unit or the specimen separating device and the interior wall of the coaxial cannula, the proximal end of the sealing element comes to act as a seal against the needle unit or the specimen separating device (the sealing element 138 maintains a seal when a vacuum is applied to the lumen 113, see Column 6, Lines 20-25 and 45-54).

Regarding claim 3, Ouchi teaches a coaxial cannula in accordance with claim 1 or 2, characterized in that when employing a biopsy device with a guide roller, provided on the distal surface of the guide roller is a stopper with sealing elements which the stopper is inserted into a counterpiece on the proximal end of the cap of the coaxial cannula (Ouchi teaches the device comprising a guide roller stopper 134, see Figure 1 (A) and (B) which comprises sealing elements 138 are inserted into respective counterpiece of the end cap of the cannula member, see Figure 1) such that the opening is closed shortly prior to placing the distal surface of the guide roller on the proximal surface of the cap of the coaxial cannula (the sealing member closes an opening prior to placing 133 in contact with 134).

Regarding claim 4, coaxial cannula in accordance with claim 1, characterized in that, when using an intermediate piece between the distal end face a guide roller with stopper and the proximal end face of the cap with counterpart, the intermediate piece has on its proximal side a counter coupling part as a type of interior bore into which the stopper of the guide roller with sealing elements is inserted and in that on the distal side the intermediate piece has a stopper with sealing elements which is inserted into the

proximal-side counterpiece of the cap of the coaxial cannula (Ouchi Figure 1 shows the device having an outer and inner member comprising an intimate (proximal portion of 130 which comprises a guide roller stopper 134 with sealing elements 138 member inserted in their respective counter pieces on the internal side of 134 surfaces, see Figure 1).

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736